

REMARKS**Status of the Claims**

Claims 36, 38-40, 42-44, 46-48, and 50-54 are currently pending in this application. Although there are no amendments to the claims, a complete listing of the claims is provided for the Examiner's convenience.

Interview Summary

Applicants would like to thank Examiner Barham and Supervisory Examiner Woodward for the courtesies extended to Applicants' representatives Charles Zeller, Jonathan Ball, and Rita Wu during a telephonic interview held July 29, 2009. The rejections under § 112, based on failure to include the feature of "aged" or "stored" perilla oil in the claims, and the rejection under § 103 for obviousness over U.S. Patent No. 5,945,109 ("Schmidt") in view of U.S. Patent No. 5,312,834 ("Yeo") were discussed. It was proposed that Applicants summarize the arguments presented during the interview and submit a request for reconsideration of the Examiner's position.

Claim Rejections**35 U.S.C. § 112, Second Paragraph**

Claims 36, 38-40, 42-44, 46-48, and 50-51 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly "failing to set forth the subject matter which applicant(s) regard as their invention." (OA, p. 4). While applicants will address the Examiner's underlying contentions in connection with the written description rejection, below, it is not necessary to do so here because the rejection under § 112, second paragraph, is facially deficient. A "rejection based on the failure to satisfy this requirement is appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims" and the "content of applicant's specification is not used as evidence that the scope of the claims is inconsistent with the subject matter which applicants regard as their invention." MPEP §2172 (emphasis added). Here, the Examiner relies, in fact, only on the instant application to support the rejection, stating that "[e]vidence that claims 36, 38-40, 42-44,46-48, and 50-51 fail to correspond in scope with that which applicant[s] regard as the invention can be found in the specification filed 3/7/2000." (OA., P. 4). As the Examiner has

cited no competent evidence in support of this rejection, withdrawal of the rejection is clearly warranted.

35 U.S.C. § 112, First Paragraph

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for reasons already of record. At issue is the following passage from page 6, lines 7-15 of the application as filed:

It is surprising and unexpected that perilla oil inhibits upregulation by PPAR agonists, as perilla oil itself contains PPAR agonists such as linolenic acid and linoleic acid. This may be attributable to perilla oil undergoing oxidation on storage due to the high content of unsaturated fatty acids. The oxidation process may alter the PPAR stimulation activity of linolenic acid and linoleic acid, causing the acids to bind to and shield the receptors, but not activate them, thereby preventing other agonists from reaching and activating the receptors.
(emphasis added)

Although the clearly equivocal word “may” is used in setting forth this theory, the passage is read by the Examiner as indicating that the perilla must be ‘aged’ or ‘stored’ to exhibit the unexpected properties of inhibiting upregulation by PPAR agonists. (OA, pp. 3-4). Based on this assumption, the Examiner rejects the claims under the first paragraph of § 112 as failing to include the allegedly critical limitations that the perilla oil be “aged” or “stored.”

The law does not support the Examiner’s interpretation. The leading case from the Court of Appeals for the Federal Circuit on this issue is Gentry Gallery v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998). In Gentry Gallery, claims to a section sofa comprising a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means. The Court held that the location of the controls was an “essential element” of the invention. Later, in Johnson Worldwide Associates v. Zebco Corp., 175 F.3d 985, 993 (Fed. Cir. 1999), however, the Federal Circuit limited Gentry Gallery, explaining that the Gentry Gallery “court’s determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on

clear statements in the written description that described the location of a claim element—the ‘control means’—as ‘the only possible location’ and that variations were ‘outside the stated purpose of the invention.’” Likewise, the Federal Circuit subsequently explained that in Gentry Gallery “[w]e did not announce a new ‘essential element’ test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.” Cooper Cameron v. Kvaerner Oilfield Products, 291 F.3d 1317 (Fed. Cir. 2002). Rather, the Court explained, “in Gentry, we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the *entirety of the specification clearly indicates* that the invention is of a much narrower scope.” Id. (emphasis added). Again, in Amgen v. Hoeschst Marion Roussel, 314 F.3d 1313 (Fed. Cir. 2003) the Federal Circuit declined to hold a patent invalid for lack of written description where the specification did not unambiguously indicate that the an allegedly omitted feature was essential to the invention. In Amgen, the defendant argued that by stating in the disclosure that the invention was “uniquely characterized” by a certain feature, that feature was “an essential element of the invention, the omission of which rendered the claims invalid for failing to satisfy the written description requirement. Id., at 1331. The Federal Circuit rejected the argument, holding that there was a “lack of *clear statements* by the patentee limiting the claimed invention” to the omitted element, and therefore the claims satisfied the written description requirement under 35 U.S.C. ¶ 112, first paragraph. Id., at 1334 (emphasis added).

It is clear from the Federal Circuit case law that equivocal statements in the specification characterizing an invention are not sufficient to give rise to a violation of ¶ 112, first paragraph, for failure to include an allegedly essential element in the claims. In the present case, the disclosure that the unexpected properties of perilla oil “*may* be attributable to perilla oil undergoing oxidation on storage due to the high content of unsaturated fatty acids” does not clearly indicate that ‘aged’ or ‘stored’ perilla oil is essential for the practice of the invention. The cited passage is, at most, equivocal and not intended to be binding and therefore does not constitute the type of “clear statement” that an omitted feature is essential to the invention required by the Federal Circuit in order to invalidate a claim under ¶ 112, first paragraph, for lack of written description. Moreover, the “entirety of the specification” does not “clearly indicate” that the invention is more narrow than what is claimed. Aside from the passage quoted above, no further reference is made to “stored” or “aged” perilla oil in the disclosure. For

instance, Examples 1 and 2, which demonstrate that perilla oil inhibits PPAR activation despite the presence of PPAR agonists, do not state that the perilla oil is ‘aged’ or ‘stored.’ Indeed, one skilled in the art would understand from reading the entire specification, including Examples 1 and 2, that the invention was not intended to be limited to aged or stored perilla oil.

The Examiner states that U.S. Patent No. 5,312,834 (“Yeo”) “teaches a composition of perilla oil . . . that should have the same activity, but the instant specification teaches that it does not” [OA, p. 3]. Applicants continue to be puzzled by this assertion, inasmuch as Yeo’s compositions are oral formulations used to treat acne and there is not the slightest suggestion in Yeo to use them topically to treat cellulite. Nowhere have Applicants characterized the claimed perilla oil as being compositionally distinct from the perilla oil referenced in Yeo. Yeo simply uses perilla oil for a very different purpose and in a very different manner.

The Examiner also alleges that “[t]he written description issue also remains in that there is no correlation between *in vivo* and *in vitro* results and the instant specification only describes treating cells with the composition, not topical application onto the skin as is instant claimed” [OA, p. 8]. While Applicants fail to see how this issue is relevant to the written description inquiry, it is respectfully pointed out that a similar contention raised by the Examiner has already been overcome in the case in connection with an enablement rejection and respectfully direct the Examiner’s attention to the response filed May 31, 2007. In that paper, Applicants demonstrated, among other things, that the USPTO has issued a patent (U.S. Pat. No. 6,852,343) for a topical oil which reduces PPAR mRNA expression for the treatment of cellulite which itself relies on *in vitro* models of PPAR regulation. Also provided was a Rule 132 Declaration of Dr. Elias which supports the fact that PPAR is understood by those of skill in the art to be implicated in the etiology of cellulite. Dr. Elias explains that “PPARgamma receptors regulate adipocyte growth and differentiation” and therefore it “follows that blocking PPARgamma receptors would be a suitable means for treating or ameliorating cellulite.” The declaration of Dr. Elias is evidence that the disclosure of the present application is convincing to one skilled in the art that inhibition of upregulation of PPAR would be an effective treatment for cellulite. In addition, Applicants submitted literature showing a connection between PPAR and the pathways implicated in cellulite formation. Accordingly, Applicants respectfully assert that the *in vitro* examples in the specification reasonably correlate with the claimed utility *in vivo*, and, in any event, the Examiner has provided no evidence to rebut this conclusion.

Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §112.

§ 103 -- Obviousness

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 5,945,109 ("Schmidt") in view of U.S. Patent No. 5,312,834 ("Yeo"). The Examiner states that Schmidt discloses a "cosmetic product for topical administration for cellulite" which may comprise "essential oils and plant extracts" including "groundnut oil." The Examiner specifically points to Example 1 of Schmidt which discloses an anti-cellulite cream comprising 10% by weight "Hardened groundnut oil." The Examiner acknowledges that Schmidt does not disclose perilla oil but relies on Yeo as teaching "a composition comprising perilla oil." The Examiner contends that one skilled in the art would have been motivated to include perilla oil, as taught by Yeo, in the anti-cellulite creams of Schmidt because Yeo teaches that perilla oil "has no side effects" whereas groundnut oil is a "known allergen." Applicants traverse this rejection.

Applicants respectfully submit that the Examiner has failed to raise a *prima facie* case of obviousness because one skilled in the art would not have had a reasonable expectation of successfully treating cellulite with perilla oil based on the combined teachings of Schmidt and Yeo. Neither of the cited references remotely suggest that perilla oil is effective in treating cellulite, or even suggest its topical application to the skin, let alone cellulite-affected skin.¹ Nor is there any teaching that perilla oil impacts a biochemical pathway implicated in the etiology of cellulite that would have given one skilled in the art an expectation that it could be beneficial for this indication. In short, the rejection is deficient for at least the reason that the art did not contain even the faintest hint that cellulite could successfully be treated with perilla oil. See MPEP § 2143.02(I) ("The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success").

¹ Yeo, the only cited reference disclosing perilla oil, relates to oral compositions for the treatment of acne. Specifically, Yeo teaches that the "composition of the present invention may be administered in the form of syrups or may be concentrated and filled in soft capsules" [col. 4, lines 49-51], and that "a satisfactory therapeutic effect can be obtained by administering one spoon (15 ml) of the composition every eight hours, three times a day" [col. 4, lines 60-66].

Despite the fact that the cited art does not remotely suggest the treatment of cellulite with perilla oil, the Examiner attempts to bootstrap an obviousness rejection by relying on Schmidt -- which teaches treatment of cellulite with "soya glycins" -- and alleging that one skilled in the art would have been motivated to include perilla oil as one of Schmidt's "customary additives" listed in column 5, lines 31-54 of that patent. In particular, the Examiner points to "groundnut oil" which is listed as a "customary additive" at column 5, line 42 of Schmidt and again to the "hardened groundnut oil" listed in the formulation of Example 1 and contends that it would have been obvious to substitute perilla oil for the hardened groundnut oil in Example 1 of Schmidt because groundnut oil is allegedly a known allergen.

The Examiner has offered no evidence whatsoever that one skilled in the art would have considered perilla oil to be generally interchangeable with "hardened groundnut oil" in topical preparations. First, the Examiner ignores the fact that Example 1 of Schmidt calls for not simply groundnut oil, but rather "hardened" groundnut oil, which means that the groundnut oil has been hydrogenated to chemically convert unsaturated bonds into saturated bonds. Second, the Examiner offers no evidence that hardened groundnut oil possesses similar physical or chemical characteristics to perilla oil that would have led one skilled in the art to consider them to be interchangeable for Schmidt's purposes. That one oil is not simply interchangeable with another oil for all purposes is evidenced by Example 2 of the present specification which demonstrates that another unsaturated oil, farnesol, does not inhibit PPAR activation. Certainly, one skilled in the art could not have had a reasonable expectation of success in using farnesol to treat cellulite.

Applicants respectfully submit that the Examiner's reasoning leads to the logical absurdity that it would have been obvious to treat cellulite with any non-allergenic oil, as the Examiner's rationale is not based on any unique property of perilla seed oil and would therefore seem to apply equally to all vegetable oils. It therefore would have been obvious to treat cellulite with olive oil or corn oil, according to the Examiner's logic. Also, the same rationale could be applied equally to the other components listed in Example 1. For example, would the Examiner contend that it would have been obvious to treat cellulite with iron oxide pigments because the formulation of Example 1 discloses the pigment titanium dioxide?

Applicants respectfully submit that the Examiner has impermissibly engaged in hindsight based on Applicants' own disclosure that perilla oil is effective at treating cellulite because there

was no recognition in the art the perilla oil was capable of treating cellulite nor any suggestion of topically applying perilla oil to an area of skin affected by cellulite. Reconsideration and withdrawal of this rejection is requested.

Having distinguished the independent claim from the art of record, Applicant submit that the claims dependent therefrom are patentable for at least the same reason. However, Applicants reserve the right to separately address the patentability of the dependent claims in the future, should that become necessary.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that another telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

Dated: August 12, 2009

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